

From: Boyd, Andrew
Sent time: 04/26/2016 03:42:16 PM
To: Schanilec, Kevin
Cc: Connery, Shannon
Subject: FW: SEP 14 - FMC
Attachments: Letter of Conveyance Final Study CEP 4 26 2016.pdf CEP Final 4 25 2016.pdf Fort Hall Final Report 12-11-2015.pdf Ltr Re Fort Hall Final Study to SB Tribes.docx Environmental Health Assessment Study review memo- 1-19-16-2.doc

From: Lizanne Davis [mailto:Lizanne.Davis@fmc.com]
Sent: Tuesday, April 26, 2016 12:18 PM
To: Boyd, Andrew <Boyd.Andrew@epa.gov>
Subject: FW: SEP 14

Dear Andy,
Per your request.
Best,
Liz

Lizanne H. Davis
Director, Government Affairs
FMC Corporation

202.956.5211 (Office) (b) (6) (Cell)
202.956.5235 (Fax)

lizanne.davis@fmc.com

From: Lizanne Davis
Sent: Tuesday, April 26, 2016 2:31 PM
To: Robert Forbes; David Heineck; Rosalind Schoof; Bill Bacon (bbacon@shoshonebannocktribes.com); Danny Stone (b) (6); 'Susan Hanson'
Subject: SEP 14

Dear All,
Today the hard copies of the attached documents will be sent to addressees listed on the cover letter. Many thanks for everyone's hard work!
Best,
Liz

Lizanne H. Davis
Director, Government Affairs
FMC Corporation

202.956.5211 (Office), (b) (6) (Cell)
202.956.5235 (Fax)

lizanne.davis@fmc.com



FMC Corporation
1600 Wilson Blvd. Suite 700
Arlington, VA 22209

202.956.5200
fmc.com

April 24, 2016

Director Office of Waste and Chemicals Management M/S WCM-127 U.S. Environmental Protection Agency 1200 Sixth Avenue Seattle, Washington 98101 [four copies]	Director, CERCLA/RCRA Program Shoshone-Bannock Tribes P.O. Box 306 Fort Hall, Idaho 83203 [two copies]
Regional Counsel Office of Regional Counsel U.S. Environmental Protection Agency Region 10 1200 Sixth Avenue Seattle, Washington 98101	Chief, Environmental Enforcement Section Environment and Natural Resources Division U.S. Department of Justice 1425 New York Avenue, N.W. Washington, D.C. 20005
Attorney's Office Shoshone-Bannock Tribes P.O. Box 306 Fort Hall, Idaho 83203	

Re: United States v. FMC Corporation, Civil. No. CIV 98-0406-E-BLW (D. Idaho)
Submittal of proposed final SEP 14 health study report and Communication and
Education Plan

Dear Sirs:

FMC Corporation (FMC) and the Shoshone-Bannock Tribes (the Tribes) have worked together for a number of years to design and conduct and keep Fort Hall Reservation residents apprised regarding the progress of the *Fort Hall Environmental Health Assessment* required under Supplemental Environmental Project (SEP) Number 14 that is an element of the July 1999 consent decree in the above-referenced action. As required under SEP 14, FMC and the Tribes designated representatives to a Study Management Team (SMT) that has administered the process, designated scientists to a Study Design Panel (SDP) that generated the health study design and reviewed its implementation, and obtained required EPA approvals for the study design, study contractor and budget allocations.

Work under this SEP is nearing completion. Enclosed are two consent decree-required documents that reflect this. The first is a draft final *Fort Hall Environmental Health*

Assessment Report prepared by Exponent, Inc., the EPA-approved contractor that conducted the study. This report has been reviewed by and reflects input from the SMT and members of the SDP. In accordance with the consent decree, the SMT is submitting this for EPA review and comment. We will instruct Exponent to develop within 30 days of receiving EPA's comments a final version of the report that takes those comments into account.

Also attached to this letter are two letters from Tribal SDP members who participated in the Study Design. These letters were discussed during a SMT conference call on February 12, 2016. FMC reserves the right to comment on these letters at a later point as appropriate.

The second document is a proposed final *Communication/ Education Plan* (CEP) under which the SMT will provide information on a prescribed schedule to Fort Hall Reservation residents regarding the health study that has been conducted, its findings, and any associated health recommendations. The planned communication and education efforts will involve not only disseminating information regarding the study but also eliciting dialogue and feedback from the Fort Hall community. The consent decree requires both EPA review and approval of this document.

We look forward to EPA's review and comments regarding the health study report and review and approval of the CEP. Thank you.

Sincerely,



Lizanne Davis
FMC SMT Representative



Danny Stone
Shoshone-Bannock Tribes SMT Representative

4-20-16

Enclosures (4)

FMC RCRA CONSENT DECREE SEP 14

Fort Hall Indian Reservation Environmental Health Assessment

Communication and Education Plan

April 25, 2016

A. Project Description

The Resource Conservation and Recovery Act (RCRA) Consent Decree (Consent Decree) in United States v. FMC Corporation (USDC Idaho, No. CIV98-0406-E-BLW) that was entered on July 13, 1999 includes FMC's commitment and obligation to conduct a study of the potential human health effects on residents of the Fort Hall Indian Reservation (Reservation) from releases of hazardous substances from the FMC Pocatello, Idaho facility. The Consent Decree designates this study as Supplemental Environmental Project (SEP) 14. The Consent Decree describes the health study and the communication and education component of this project as follows:

The Study will evaluate both direct human exposure pathways (air, water and soil) and indirect pathways (food, plants, fish and animals). In accordance with EPA's SEP Policy, the project will provide diagnostic, preventative and/or remedial components to human health care.

A key aspect of the project includes implementing a communication and education program to inform and educate the Tribal community regarding all stages of study implementation, results and recommendations.

This Communication and Education Plan (CEP) has been developed in accordance with Consent Decree requirements, and includes but is not limited to the following:

1. Identification of the individuals and contractors that will be conducting the various components of the communication/education effort, their responsibilities, and the qualifications of the scientific experts involved in this effort;
2. A description of the CEP objectives and the actions that will be taken to achieve those objectives; and

3. A schedule for completing the communication/education effort and reporting results to EPA.

B. EPA Review and Approval of the CEP

The Consent Decree specifies that this CEP and any future revisions to it require EPA review and approval. Although the Consent Decree provides that EPA review and approval will occur only after the SEP 14 health study report has been completed, the SMT has taken efforts throughout the project to keep the Tribal community and all the Reservation residents informed regarding the study design and its implementation. Following EPA review and approval of this CEP, the SMT will ensure that it is fully implemented.

C. The SEP 14 SMT Serves As the CEP Team

The SMT responsibilities include administration of the SEP 14 schedule and budget, approval and management of contractors, and management of the CEP. The SMT is composed of an equal number of representatives appointed by the Shoshone-Bannock Tribes and FMC.

In 1999, the SEP was organized with a Study Management Team, a Communications and Education Team, and a Study Design Panel. Representatives from both FMC and the Shoshone- Bannock Tribes represented each group. The following were representatives:

Study Management Team

Susan Hanson- SBT
 Hobby Hevewah- SBT
 Marty Reape, Ph.D- FMC
 Paul Yochum- FMC

Communication and Education Team

Jamess Skunkcap – SBT
 Jim Cutler- SBT
 Lizanne Davis- FMC
 Laverne Sheppard- FMC

Study Design Panel

Jack Mandel, PH.D, MPH- FMC
 John Moore- FMC
 Tom Gesell, Ph.D, CHP- FMC
 Gary Rischetelli MD- SBT
 James Lai, PhD- SBT
 Thomas Becker, MD, PhD- SBT
 William Lambert, PhD- SBT
 Chad Colter- SBT
 Delbert Farmer- SBT
 Daniel Warjack- SBT

The SMT members as of the date of this CEP are the following:

FMC Representatives (FMC SMT):

- Lizanne Davis, Director, Government Affairs
- Robert T. Forbes, Director, Environment
- David M. Heineck, Attorney (Summit Law)
- Rosalind Schoof, Toxicologist, Ramboll-Environ US Corporation

Shoshone-Bannock Tribal Representatives (TSMT):

- Susan Hanson, Tribal Consultant
 - Hobby Hevewah, Tribal Member/Cultural Consultant
 - Open,
 - Daniel Stone, Esq. Tribal Fish and Wildlife Department/
Tribal Natural Resource Specialist
- Former Tribal Participants
- Talia Martin, SMT
 - John Kutch, SMT
 - Blaine Edmo, Tribal Coordinator
 - Nancy Murillo, Tribal Coordinator

Current Members of the Study Design Panel:

- Tom Gesell, Ph.D, CHP - FMC
- Frank Gilliland, MD, Ph.D - FMC
- Jay Gandy, Ph.D - FMC
- Peter Orris, MD, Ph.D - SBT
- Jerry Leiken, MD - SBT
- Ray Kary, SBT
- Jack Mandel, Ph.D, MPH – FMC -- voluntarily recused due to conflict

The Consent Decree requires designation of a Communication and Education Team to implement the CEP. The SMT has determined that it will serve as the Communication and Education Team. The SMT has developed and will implement the CEP in a manner that is fact-based and adaptive, based on Reservation resident inquiries and feedback, and thorough in terms of informing and educating Reservation residents regarding the SEP 14 health study evaluations that have been conducted and the study results. All CEP activities will be reviewed and approved in advance by the SMT.

D. CEP Goals and Objectives

The objectives of this CEP are to meet Consent Decree requirements to inform and educate the Tribal community and all Reservation residents regarding the SEP 14 health study evaluations that have been conducted, their results, and recommendations based on those results.

Outreach to meet the CEP objectives will include the actions described below. All of the actions described below, except for those actions that may be taken by the Fort Hall Business Council as described in Section E.1, must be approved in advance by the overall SMT.

E. CEP Implementation Schedule

1. Fort Hall Business Council (FHBC) Briefing: *within 120 days of EPA approval of the CEP*

A formal briefing to the FHBC will be jointly scheduled by the TSMT and FMC SMT members and Exponent and held prior to public dissemination of the study findings. If the FHBC supports the SMT taking the communication actions listed below, the SMT will complete those actions in accordance with the stated schedule. If the FHBC instead determines that it will assume control of communicating the study results to members of the Fort Hall Tribal community and Reservation residents, the FHBC will take whatever communication actions it determines are appropriate and the SMT will be discharged from any requirement to take the actions described below and FMC's obligations under SEP 14 will be deemed complete.

2. Newsletter: *developed within 60 days of EPA approval of CEP, and released within 30 days following FHBC briefing*

The SMT will develop a newsletter detailing the studies associated with SEP 14. The newsletter will be drafted so as to be readily understandable to the community, and it will be distributed by the following means:

- US mail to all residents of the Reservation through bulk mail delivery;
- Placing copies at locations frequented by Reservation residents;
- Posting to the Reservation website; and
- Placement in other local publications.

3. Electronic Media: *developed within 60 days of EPA approval of CEP, and released within 30 days following FHBC briefing*

Electronic media such as email distributions and Facebook postings may be used as authorized by the SMT to inform Reservation residents of public meetings, the newsletter, and other SEP 14-related information as appropriate. All material developed and responses to questions/comments will be jointly developed and approved by the SMT prior to release of that information to the public.

4. Newspapers: *developed within 60 days of EPA approval of CEP, and released within 30 days following FHBC briefing*

The SMT will prepare a press release and/or letter to the editor summarizing SEP 14 study results for the **Sho-Ban News**, **Idaho State Journal**, **Power County Press**, and **Blackfoot Morning News** as the SMT determines appropriate.

5. Website and Internet: *developed within 60 days of EPA approval of CEP, and released within 30 days following FHBC briefing*

All studies, work plans, newsletters, relevant health information, and news stories associated with SEP 14 will be available in electronic format for public review through the Shoshone-Bannock Tribes' website and the FMC Pocatello website.

6. Reservation Meetings: *commencing within 45 days of FHBC briefing*

The SMT will schedule 2 sequential informational meetings for Reservation residents regarding the SEP 14 health study to describe the evaluations that have been conducted and their results, and respond to questions.

The meetings will be staffed by at least one FMC SMT and TSMT member, and one or more representatives of the scientific consulting firms that conducted the study (specifically, Dr. David Hoel of Exponent and/or Dr. Dominik Alexander of Exponent's subcontractor EpidStat Institute). The meetings will include the following:

- Exponent and EpidStat will provide a summary of the SEP 14 health studies that have been conducted, including the Oregon Health and Sciences University report that was issued in April 2006 and the Exponent study report issued on December 11, 2015;
- The SMT members who attend the public meetings will prepare a summary of the issues raised during the meetings and the responses that were provided by Exponent and/or EpidStat.

All SEP 14 meetings, whether open to all Reservation residents or limited to members of the Shoshone-Bannock Tribes, will utilize identical informational material. During these meetings,

the SMT will only respond to questions regarding the study scope, schedule, facts about the studies, and execution. All other questions (e.g., regarding technical aspects of the studies, rationale for the design, etc.) will be recorded and answered by Exponent and/or EpidStat at the meetings, or they will develop responses after the meetings conclude. Responses developed after the meetings will be communicated through one or more of the means described in this section of the CEP. The SMT will not speculate, postulate, or theorize responses to questions that arise in such meetings on matters for which the SMT is not directly responsible and which are outside the scope and responsibilities of the SMT specified in the Consent Decree.

Exponent®

Exponent®

**Fort Hall Environmental Health
Assessment Study**



Fort Hall Environmental Health Assessment Study

Submitted to:

Study Management Team
Prepared by

Exponent
Health Sciences
Alexandria, Virginia 22314

December 11, 2015

© Exponent, Inc.

Contents

	<u>Page</u>
List of Figures	iii
List of Tables	iv
Executive Summary	v
Background	viii
Summary of Phase 1 and Phase 2 Development	1
Scientific Foundation	1
Review of the Project Portal and Other Background Information	2
Site Visits, Community Discussions, Tribal Council Meetings, and Participation Survey	2
Willingness-to-Participate Survey	3
Development and Approval of Phase 2 Plans	5
Phase 2 Methodological and Analytical	8
Phase 2 Analyses: Cancer, Mortality, and Sentinel Events	11
Cancer Incidence Study	11
All-Cause Mortality Study	18
Sentinel Health Events	22
Childhood Asthma	23

Attachment A Results of Willingness-to-Participate Survey

List of Figures

	<u>Page</u>
Figure 1. Cancer incidence and cancer mortality among American Indians and Alaska Natives during 1999–2011	13
Figure 2 Idaho Counties	14
Figure 3 Map of Fort Hall Reservation and Surrounding Counties	15
Figure 4 Cancer Incidence (2007–2011) among American Indians in Fort Hall and Remainder of Idaho CHSDA Counties	16
Figure 5 Cancer Incidence (2007–2011) among American Indians in the three Fort Hall Counties, and Cancer Incidence in the Remaining Idaho Counties	18
Figure 6 Age-Adjusted Total Mortality Rates for American Indians and Alaska Natives during 1999–2012	19

List of Tables

	<u>Page</u>
Table 1. Cancer Incident Cases and Cancer Deaths among American Indians and Alaska Natives during 1999–2011	12
Table 2. Most Common Cancer Sites among American Indians in Idaho (1999–2011)	13
Table 3. Cancer incidence (2007–2011) among American Indians in Fort Hall and Remainder of Idaho CHSDA Counties	16
Table 4. Cancer Incidence (2007–2011) among American Indians in the Fort Hall census tracts, and Incidence in the Fort Hall counties of Bannock, Bingham, and Power	17
Table 5. Cancer incidence (2007–2011) among American Indians in the three Fort Hall counties, and cancer incidence in the remaining CHSDA Idaho counties	17
Table 6. Total Mortality and Age-Adjusted Rates for American Indians and Alaska Natives during 1999–2013	19
Table 7. Major Causes of Death in American Indians and Alaska Natives (1999–2013)	20
Table 8. Changes in Age-Adjusted Mortality Rates for Major Causes of Death in American Indians and Alaska Natives (1999–2005 compared to 2006–2013)	20
Table 9. Major Causes of Death in American Indians and Alaska Natives (1999–2013)	21
Table 10. Major Causes of Death in American Indians and Alaska Natives (1999–2013)	22
Table A-1. Characteristics of Survey Participants in Fort Hall, Idaho (August–October 2012), n=351	A-1
Table A-2. Likelihood of Answering Questions on the Following Topics in a Future Questionnaire	A-3

Executive Summary

We have completed the analytical phase of the Fort Hall Indian Reservation community health assessment. According to the approved study work plan, we have evaluated the feasibility of conducting four health assessments (i.e., cancer, mortality, sentinel events, and asthma), and have made significant efforts to carry out the analyses for each of the four assessments while taking into account the limitations discovered during the feasibility phase of this research.

1. **Cancer:** The basis for assessing cancer risks involves the concept of disease rates, which are the numbers of cancer occurrences that are observed in a given population of a specified size. Specifically, cancer incidence is a measure of disease burden that describes the occurrence of new cancer cases in a given study population in a given time period. The Centers for Disease Control and Prevention (CDC) of the Public Health Service provides support to most of the State Cancer Registries. Besides helping to maintain the registries, the CDC sees that the data are of high quality through the National Program of Cancer Registries (NPCR), which was established in 1992. Idaho's Registry began in 1979 and joined the NPCR program in 1994. The North American Association of Central Cancer Registries (NAACCR) is an oversight group that began in 1987. Data down to the county level began in 1995, and the NAACCR certifies the quality of a State's data. The registries have three levels of certification, with gold being the highest. The Idaho Registry has received a gold rating every year since this rating system began. In an ideal setting, and to increase study validity, data should be ascertained at the most specific level possible. As indicated, most cancer data are readily available at the county level. However, the extensive work of Chris Johnson, who is an epidemiologist in charge of the Idaho Cancer Registry, his geo-coding of cancer cases, and the availability of U.S. census data at the census tract level during the period 2007–2011 have facilitated a cancer incidence analysis of the highest quality at the community level.

Based on geo-coded cancer incidence data for the years 2007–2011, the analyses clearly show that cancer incidence is lower in the Fort Hall Indian Reservation (referred to as “Fort Hall” in this report) census tract areas than in both the surrounding three counties and the remaining areas of the State of Idaho. For all cancers combined, the rate for Fort Hall is about one-half that of the remainder of Idaho, with lung cancer being less than one third.

2. **Mortality:** The National Center for Health Statistics (NCHS) of the CDC collects and codes all death certificates in the United States. These data, coupled with data from the census bureau, then provide mortality rates for various causes of mortality. The data are available by location, age, race, gender etc. Using these data, one can estimate and compare mortality rates for a given cause of death by age, gender, race, etc. The data are publically available through the CDC website. Thus, cause-of-death rates were compared between the Fort Hall counties and the remainder of Idaho, or selected comparison counties. Although these data are not geocoded, this is standard methodological practice to evaluate the mortality experience in a community. This analytical approach is in concert with hundreds of scientific publications on community health assessments.

In general, the mortality rates for the Fort Hall counties are greater than those of the other Idaho counties. However, the Fort Hall counties include individuals who are not in Fort Hall, while the cancer incidence analyses used the more accurate census-tract data. Fewer differences are observed when comparing Fort Hall mortality rates with Contract Health Service Delivery Areas (CHSDA) counties. Of the mortality rates observed to be elevated, it appears that they are of diet- and lifestyle-related etiologies, such as type 2 diabetes, accidents, and alcohol-related deaths. In an effort to make a more similar and representative comparison, mortality rates in Fort Hall were compared with mortality rates in the population of American Indians in Fremont County, Wyoming. The Wind River Indian Reservation is in Fremont County and is the home of the Eastern Shoshone and Northern Arapaho tribes of North America, while the Fort Hall area is home both the Shoshone and Bannock tribes. Overall, and for each cause of mortality, the rates were higher in the Wyoming county comparison population. The one exception is endocrine and metabolic disease mortality, which is primarily a result of diabetes pathology.

3. **Sentinel Events:** In epidemiologic parlance, sentinel events involve the occurrence of a rare disease known to be associated with a specific exposure. These disease occurrences are typically identified through a framework of surveillance networks over a lengthy time period. In the current Fort Hall community health assessment, we have to rely on the identification of greater-than-expected occurrences of certain cancer outcomes or causes of death in our analyses, to determine whether a sentinel event outcome can be classified as unique to the specific Fort Hall community setting. Thus, given our current methodological and analytical protocol, the occurrence of an excess number of specific cancer cases or causes of death was identified concurrently with our cancer and mortality studies.

Based on the cancer analyses reported in this document, no sentinel cancer events were observed. In fact, most cancer rates were less than the comparison populations. Similarly, no sentinel mortality events were observed based on the analyses reported in this document.

4. **Asthma:** This health condition is the most challenging to evaluate, for a number of reasons. A few of these challenges are as follows: (1) there is no county, community, or state registry for the identification and collection of asthma cases; thus, we have no existing and publicly available repository for validated data with which to conduct a systematic analysis; (2) the diagnosis of asthma is highly variable, and is often subjective in terms of incidence classification, which complicates interpretation of the data; (3) in the absence of publicly available registry data, it would be necessary to ascertain individual-level medical information from the entire study catchment area in Fort Hall; and (4) we attempted to ascertain the willingness to participate in a community health study (sending more than one thousand questionnaires); feedback was well below acceptable limits, and the number of responses that shared medical information was unacceptably low. Thus, the only relevant and feasible endeavor (though of limited scientific validity) would be to compare visits pertaining to asthma before and after plant closure (as discussed with the Study Design Panel). However, this would require the aid of a health liaison from the Fort Hall community, and participation by the clinic in Fort Hall. We have made efforts to reach out to staff to pursue this option, but feedback was limited, and it appears that medical record storage formats vary (electronic vs. written) and such information may not be reliable. Therefore, it is not scientifically reasonable to pursue analytical ventures for asthma based

on the information available for this study. These methodological challenges and limitations were discussed at length with the Study Design Panel, which they acknowledged.

Background

A request for proposal (RFP) for the Fort Hall Health Assessment Study was issued on January 28, 2011. As described in the RCRA Consent Decree, the project is *“a study of the potential human health effects on residents of the Fort Hall Reservation that may have resulted from releases of hazardous substances from RCRA waste management units and other sources at the FMC Pocatello facility. The study will evaluate both direct human exposure pathways (air, water and soil) and indirect pathways (food, plants, fish and animals). In accordance with EPA’s SEP Policy, the project shall provide diagnostic, preventative and/or remedial components to human health care.”*

A Study Design Panel (SDP) of experts was selected by a Study Management Team (SMT), consisting of an equal number of representatives from each of the Shoshone-Bannock Tribes and FMC Corporation. The RFP identified four potential studies, each of which was to be conducted in two phases:

- **Phase 1** - Explore the feasibility of the consultant being able to obtain from existing sources sufficient health data and other information to define the cohort and refine the methodology for conducting the study.
- **Phase 2** - Complete the study utilizing the refined methodology developed in Phase 1, in consultation with the SEP 14 SMT.

The RFP described the four study questions to be addressed as follows:

- **Cancer Incidence** - Have members of the study cohort exposed to releases from the FMC plant during the years between 1949 and 2001 experienced significantly different rates of cancer incidence as a result of that exposure than an appropriate comparison population(s) as identified and defined during the Phase 1 feasibility work?
- **All-Cause Mortality** - Have members of the study cohort exposed to releases from the FMC plant during the years between 1949 and 2001 experienced significantly different rates of deaths as a result of that exposure than an appropriate comparison population(s) as identified and defined during the Phase 1 feasibility work?
- **Childhood** - Did early life exposures to Particulate Matter (PM) from the FMC plant significantly change the risk for new onset asthma or asthma exacerbations among children residing on the Fort Hall Reservation from 1990 to 2005 as a result of that exposure? Did closure of the FMC plant in 2001 significantly affect rates of new onset asthma and prevalence of exacerbations among children residing on the Fort Hall Reservation?

- **Sentinel Events** - Did exposure to releases from the FMC plant during the years between 1949 and 2001 lead to distinct and specific adverse health events as a result of that exposure?

The proposal submitted by Exponent was selected and the study was begun. During Phase 1 Exponent evaluated the technical feasibility of conducting each study and recommended those that were technically feasible and could be conducted within the available project budget. During Phase 1, Exponent submitted two progress reports, one dated October, 24, 2012 and a second dated August 30, 2013.

This final report summarizes the community health assessment of residents in Fort Hall, Idaho. Exponent has collected and reviewed hundreds of documents, reports, and peer-reviewed articles pertaining to Fort Hall, the FMC former elemental phosphorus processing facility near Pocatello, Idaho, studies conducted among Native American populations, and environmental and community health studies among all populations. We submit this final report as a summary of the methods and analyses we conducted, and the results and findings of the Fort Hall community health assessment, where feasible. The following sections describe the steps we took in Phase 1 and Phase 2 and provide the results of our analyses and overall findings.

Summary of Phase 1 and Phase 2 Development

The Fort Hall Environmental Health Assessment Study included two phases. Four main tasks were completed as part of Phase 1:

1. A review of existing background information, including the documents that the SMT posted to an electronic repository referred to as the Project Portal
2. Identification and assessment of the study cohort that would be evaluated for the four health studies:
 - a. All-cause mortality
 - b. Cancer incidence
 - c. Asthma
 - d. Sentinel health outcomes
3. Formulation of the preliminary observations, including:
 - a. The study design and associated methodological and analytical limitations
 - b. Environmental
 - c. Subject interviews
4. Recommendation for decision of a detailed study and design of a Phase 2 study.

Scientific Foundation

The fundamental scientific approach used by Exponent is consistent with other community health evaluations, and we incorporated information learned from an exhaustive review of peer-reviewed literature and public/governmental reports pertaining to conducting research among Native American populations. Each study has unique and intrinsic characteristics, and the Fort Hall community is no different. In fact, evaluating the community health status of Fort Hall residents presented greater challenges due to distinctive aspects of the social and medical infrastructure, socio-demographic dynamics, and within-population variation. Indeed, the Fort Hall reservation is composed of tribal and non-tribal members, and it was important to examine the health status of all residents. However, it was fundamentally and scientifically necessary to stratify analyses as well, to account for the aforementioned demographic distinctions. The primary components of the Phase 1 effort involved a comprehensive feasibility assessment to determine the likelihood conducting certain types of studies.

Review of the Project Portal and Other Background Information

Exponent health scientists with expertise in exposure assessment and epidemiology reviewed numerous documents that the SMT posted in the Project Portal electronic repository, for the purpose of identifying useful information to conduct the four proposed health studies of all-cause mortality, cancer incidence, asthma, and sentinel health events. However, the information contained within the Project Portal was only used to a limited extent in designing the studies; such information was used to facilitate interpretation of the data analyses and better understanding the risk factors. As indicated, Exponent health scientists reviewed relevant, peer-reviewed scientific literature, environmental data collected under EPA regulations, and U.S. census data for the same purpose. The documents in the Project Portal contained information on past and current residents of the Fort Hall Reservation, their vital status (at the macro level), and relevant environmental and exposure assessment data. However, in isolation, this information could not be used to enumerate a community cohort.

We obtained U.S. census data on demographic, economic, and educational characteristics of residents of the Fort Hall Reservation and Off-Reservation Trust Land in 2006–2010 (based on the annual American Community Survey) and 2010 (based on the decennial census). Although this information cannot be used to specifically examine individual-level exposures and outcomes, it was beneficial when interpreting the statistical analyses used to evaluate whether a reported exposure may be associated with an outcome, in the event that an excess risk is observed in the Fort Hall community.

Site Visits, Community Discussions, Tribal Council Meetings, and Participation Survey

Three onsite meetings were made by the primary study team, with the objectives of:

- Viewing the facility location, environmental landscape, and community infrastructure
- Meeting the tribal leaders and key community members (e.g., Tribal Business Council)
- Visiting key locations, such as the Records and Tribal Health offices
- Assembling background data and information, including research on resident/population demographic characteristics, healthcare facilities, and economic status
- Enhancing population feedback, involvement, and participation through several community meetings, question-and-answer sessions, and public forums.

The first visit involved meetings with the Study Management Team to discuss the necessary steps in conducting the feasibility assessment, and the information required to carry out the study. In addition, Exponent scientists met with key community members of various tribal departments. The second visit involved on-site presentations to both the Tribal Business Council and the Fort Hall community. The information in the presentation was used to make posters describing the study protocol for the community residents to review. The third visit involved discussing the community health study in an open forum at the Fort Hall High School and the Fort Hall dome room.

The purpose of these sessions was to help the residents better understand the nature of the study and to enhance community involvement. In addition, the study was discussed in the Chamber Room of the Tribal Business Council at Fort Hall, for which full support was received from the tribal leaders. Importantly, the Tribal Leaders endorsed the study and indicated that they would bolster community participation. Our researchers had the opportunity to interact directly with community members, to communicate the importance of the study and to initiate and increase their interest in the study.

Of importance, Exponent researchers did not focus on communicating with tribal members over non-tribal members. All community interactions were open to the public, advertised, and free for all to attend. Unfortunately, despite strong publicity, our efforts, and the efforts of certain tribal leaders and members of the Study Management Team (SMT), the community meetings were poorly attended. Few questions or comments were offered by the attendees at these meetings. As discussed below, additional efforts to engage the community via a willingness-to-participate survey also failed to elicit much response. Community involvement is widely considered an important factor when evaluating the morbidity and mortality experience of a population. However, other types of scientifically credible and valid analyses can be conducted without individual participation. Indeed, despite the limited community participation, we were able to conduct health and disease analyses using well-established scientific guidelines.

Willingness-to-Participate Survey

Based on information obtained from our site visits, review of the Project Portal, scientific research efforts, community and SMT correspondence, and lack of meeting attendance, Exponent created (with SMT approval) a short, non-invasive Willingness-to-Participate Survey. This was an anonymous survey mailed to all (i.e., tribal and non-tribal) residents of the Fort Hall Reservation to determine whether they would be willing to complete a detailed questionnaire and/or participate in interviews, and to release medical information that would allow the research team to ascertain important information regarding residential history, diet, medical

conditions, and lifestyle.¹ This approach is a common research methodology in community and environmental epidemiologic studies.

The survey consisted of two pages, along with a one-page invitation letter describing the purposes of the survey and the overall Fort Hall Environmental Health Assessment. The survey was developed by a team of experienced Exponent epidemiologists in consultation with SMT members. The survey elicited information on overall willingness to participate in the current survey (and, if applicable, reasons for non-participation), tribal status, age, gender, place of residence, household size, and willingness to answer questions about residential history, diet, food sources, water sources, use of local plants in ceremony, occupation, tobacco smoking, physical activity, alcohol consumption, access to health care, and current health for oneself and one's household members. To maximize participation, the survey was designed to be brief, anonymous, clearly relevant to Fort Hall residents, and easy to return in an included pre-paid, pre-addressed envelope. We made every effort to make the process as easy as possible (i.e., postage paid and pre-addressed return envelope) for the community members. The SMT developed a flyer describing the overall purpose of the Fort Hall Environmental Health Assessment Study, illustrating the steps in Phase 1, and encouraging residents to "get involved by answering surveys in the mail."

Approximately 3500 surveys were sent via mail. Only ten percent were returned. Of those returned ninety percent agreed to participate, but not all of these respondents were willing to share all types of information (e.g., medical information, alcohol use, etc.) (see Attachment A, Tables A-1 and A-2 for the survey results).

Due to the very low response rate, we concluded that it was not feasible to ascertain individual-level information for the Phase 2 analyses of the Fort Hall Environmental Health Study. In particular, we were not able to enumerate a complete or representative cohort of current and past residents of the Fort Hall Reservation based on "individual-level" data. Furthermore, in the absence of such data, we were not able to examine the associations between dietary, lifestyle, socioeconomic, and clinical factors. Indeed, when following the established scientific method to conduct a human health study using individual-level data, it is necessary to achieve a moderate to high participation rate (ideally over 50%) to evaluate a representative sample of the population. If this is not achieved, the conduct and results of the study could be severely

¹ Prior to dissemination of the survey, Exponent researchers took the necessary steps to go through the formal process of protecting individual's' privacy. Indeed, following scientific protocol for evaluating human subjects and in accordance with tribal recommendations, Exponent submitted the required Institutional Review Board (IRB) information to the Northwest Portland Area Indian Health Board. Key Exponent investigators were required under IRB protocol to complete the Collaborative Institutional Training Initiative (CITI), which involved a comprehensive online course on conducting human research, with a focus on Native populations. Exponent investigators received an exemption letter from the Portland Area Indian Health Service IRB to submit a "Willingness to Participate" survey to Fort Hall residents. Exponent successfully registered with IRB net, which is the online IRB document repository for all activities related to conducting studies on human subjects. In addition to obtaining IRB exemption status and SMT approval, the willingness -to -participate survey was approved by the Fort Hall Business Council. Note: that the same IRB was used to conduct the formal analyses.

affected by selection bias (a non-representative analytical study sample), which would invalidate the study. More details on issues related to community surveys and an evaluation of the feasibility of increasing responses was provided in the second progress report.

In light of the above limitations, we moved forward with population – rather than individual – analytical studies. This methodology is highly utilized and well-accepted to perform health and disease analyses in a community setting. Because of the individual-level data limitations, we were unable to perform analyses of asthma and sentinel events as laid out in the original protocol. We were, however, able to use standard epidemiologic techniques to evaluate the occurrence of cancer and causes of mortality in the Fort Hall community by using population-based data in the absence of individual-level data as mentioned above. Thus, we moved forward with cancer and mortality analyses in Phase 2, with an effort to continue with a modified approach to evaluate asthma and sentinel events. The methodology for Phase 2 is described below

Development and Approval of Phase 2 Plans

Although detailed information from community members were not available, during Phase 1, we still determined that it was feasible to conduct Phase 2 of the Fort Hall Environmental Health Study for the occurrence of cancer and the causes of mortality using the state cancer registry data and information from the national death index. With this type of analysis, no individual-level data are required. Rather, “population-based” cancer data and national death index data are identified in the registries representing Fort Hall residents, and are compared with external populations, such as neighboring counties, the state, the United States, and more appropriately other native populations. This type of external comparison analysis will indicate whether certain types of cancer or causes of death are greater or less than what is expected in a community or specific geographic region. In the absence of individual-level information, this is the optimum scientific methodology to conduct a community health study. This type of analysis can feasibly be performed for cancer (all types) and mortality (all causes of death). In summary, Exponent conducted the most relevant and appropriate types of cancer and mortality analyses using validated population-based data from governmental and state registry sources.

However, for the proposed studies of asthma and sentinel events, it was determined to be infeasible using the approach that was proposed in the original protocol. Unfortunately, detailed individual-level information is necessary to conduct an appropriate analysis for asthma, since there is no registry that compiles the occurrence and severity of asthma at the community level. Without community participation, this analysis would not be feasible. In addition, the same type of information is required to appropriately evaluate the incidence of sentinel events. Cancer and mortality-related sentinel events could be evaluated in the registry analysis, however, non-cancer or non-fatal sentinel events could not be examined without adequate community participation. The second progress report documented the Phase 2 studies that were developed by Exponent in consultation with the SDP and subsequently, reviewed and unanimously approved by the SMT. The proposed study design was submitted to EPA in a letter dated October 14, 2013.

The planned studies and a brief description of how they were executed or determined to be infeasible is provided here:

Cancer Incidence Study – This study was planned to assess the cancer experience of the Fort Hall Reservation population that had potential exposure from FMC releases from 1949 through 2001 compared to the cancer incidence of non-exposed controls. It was envisioned that Exponent would work with local health providers and agencies to identify and access cancer incidence data. This includes clinical records, cancer registry data, National Death Index, state, local and tribal information and health data as is pertinent to the study. To accomplish this study Exponent researchers analyzed clinical information from the cancer registry and National Death Index for tribal, local, and state residents. The results of these analyses are described in detail in a forthcoming section.

All-Cause Mortality Study – This study was planned to compare the mortality experience of the Fort Hall Reservation population that had potential exposure from FMC releases from 1949 through 2001 compared to the mortality experience of non-exposed controls. Exponent was expected to assess the federal and local mortality data, the National Death Index, and other state, local and tribal sources. It was expected that the mortality data of the tribes would be analyzed utilizing standard epidemiological methods for comparison to other populations. Exponent researchers analyzed local mortality data among tribal, local, and state residents using the National Death Index. The results of these analyses are described in detail in a forthcoming section.

Childhood Asthma – This study was planned to determine whether particulate releases from the FMC plant contributed to the development of new onset asthma or asthma exacerbations in children residing on the Fort Hall Reservation. The plant closure in 2001 offered an opportunity to contrast risk for cohorts of children born before and after plant closure. It was initially anticipated that pertinent information and health data would be obtained through personal contacts (interviews, questionnaires, etc.) of incidence in the study group; however, as described above, the low response to the Willingness to Participate Survey led to the conclusion that detailed individual-level information could not be compiled. Such data is necessary to conduct an appropriate analysis for asthma, since there is no registry that compiles the occurrence and severity of asthma at the community level. Without community participation, this analysis would not be feasible. Nevertheless, Exponent made an effort to reach out to local medical and health liaisons in an effort to compare rates of new onset asthma within the Fort Hall Indian Health Services clinic before and after plant closure. Exponent discussed these efforts with the tribal council and had several discussions with tribal health staff. However, it was subsequently discovered that the medical records were in variable formats and a representative sample of records were unavailable. Furthermore, a lack of informed consent precluded a medical chart abstraction analysis.

Sentinel Health Events – Health consequences of chronic environmental exposures can be manifested in a variety of ways that make it difficult to determine a precise association. However, there exist a limited number of disease states whose occurrence serves as a biologic marker of such environmental exposures. The study plan called for development of a list of potential sentinel health events (SHEs) relevant to the Fort Hall Reservation population, collecting information on the prevalence of each potential SHE from all known clinical databases, and comparing the prevalence rates to expected rates. Exponent reviewed the literature and discussed certain outcomes with community residents. As discussed above, no individual-level data were available, making it infeasible to evaluate non-cancer or non-fatal sentinel events. The results the cancer and mortality analyses were examined to determine whether any possible sentinel health outcomes exist.

Phase 2 Methodological and Analytical

Work conducted for Phase 2 incorporated information reviewed from the Project Portal, along with health data and other information ascertained for the purpose of a health analysis among Fort Hall residents. Exponent researchers conducted registry and national database analyses and did not collect additional environmental sampling data or biological samples, including blood and/or urinary measurement, and did not perform clinical or diagnostic procedures. After completion of Phase 2 of the research, Exponent moved forward with many of the critical analytical components of Phase 2.

Using a registry, we enumerated the cohort retrospectively with confirmed and validated outcomes with a high-degree of follow-up. These data are of high validity because of the compulsory reporting structure of cancer cases to the Idaho Cancer Registry and of mortality to the National Death Index (NDI). “Population-based” cancer data and NDI data were identified in registries representing Fort Hall residents. These data were compared with external populations, such as neighboring counties, the state of Idaho, the United States, and perhaps more appropriately, other native populations. This type of external comparison analysis indicated whether certain types of cancer or causes of death are greater or less than what is expected, and this is a well-accepted and commonly used design to evaluate the health status of a community. In the absence of individual-level information (rare for a large, community-based study), this is the optimum scientific method of conducting a community health study.

Researchers attempting to evaluate the health of a community are faced with numerous challenges, such as fully enumerating a cohort population within scientifically relevant demarcated geographic boundaries, obtaining consent from willing study participants, and validating cases of disease. Indeed, researchers assessing the health of a Native American population are faced with the same challenges, in addition to potential obstacles associated with cultural sensitivities, researcher trust, community involvement, record keeping, and ascertainment of validated medical information.

The medical literature indicates that many Native American populations typically have a distinct constellation of lifestyle, cultural, and genetic factors that differentially affect morbidity and mortality rates of various diseases, compared with background rates of risk factors and health outcomes in the general population (Cobb and Paisano 1998; Galloway 2005).^{2,3} In addition, many Native American tribes living in rural areas do not seek routine medical care, making it extremely difficult to evaluate the occurrence of adverse health effects. Because of these inherent challenges, we conducted an in-depth literature review to explore the methodological practices employed by previous investigators. More specifically, we reviewed a series of community health studies conducted among Native Americans residing in various geographic

² Cobb N, Paisano RE. 1998. Patterns of cancer mortality among Native Americans. *Cancer* 83:2377–2383.

³ Galloway JM. 2005. Cardiovascular health among American Indians and Alaska Natives: Successes, challenges, and potentials. *Am J Prev Med* 29(5S1):11–17.

regions in which the health outcomes assessed included cancer, cardiovascular disease, substance abuse, cognitive impairment, and asthma, among others.

Throughout the studies, the methods used to collect data varied greatly (e.g., use of health care records, participatory questionnaires, in-person interviews, health databases such as state cancer registries, the Surveillance Epidemiology and End Results program, and the National Death Index). After exploring the various non-registry resources used to collect data, there were several limitations due to sub-optimal participation rates, small population size, and lack of consistent and validated case reporting. In the matter of registry studies, selection of an appropriate comparison population was of concern.

In 2001, the National Cancer Institute funded three centers (and one coordinating center) to test the feasibility of establishing a cohort of American Indian (AI) and Alaska Native (AN) people. The cohort was named “EARTH” by participating tribal organizations. We acknowledge this cohort here, because it represented a prime example of the monumental undertaking (e.g., an extremely large number of governmental researchers, technical and logistical resources, and grant funding) necessary to conduct such an evaluation. Three grants were funded in Phase I of the EARTH study, totaling approximately \$6,000,000. Their 4-year proposal focused on the development of an AI/AN cohort to obtain a better understanding of the disparity in disease rates and risk factor knowledge that exist between AI/ANs and U.S. white populations. Note: to our knowledge, it appears that virtually all publications from the EARTH project have focused on social characteristics, lifestyle factors, and risk factors. We were unable to identify any published analytical studies from this cohort that examined the association between risk factors and cancer, cardiovascular disease, mortality, or other disease outcomes (aside from a few self-reported health outcomes). This was rather disappointing, because such a large study could have served as a useful tool for methodological design and comparison of results. An objective of the AI/AN cohort was to determine how diet, physical activity, and other lifestyle and cultural factors relate to the development and progression of chronic diseases such as cancer, cardiovascular disease, stroke, type 2 diabetes, chronic lung and respiratory diseases, and related mortality from these diseases. To our knowledge, their proposed objective did not include an environmental or occupational component. It is clear that our study plan cannot replicate the methods of the EARTH cohort (for example, they obtained biological samples from study subjects).

In a registry-based study, individuals in a defined study population are linked to an existing disease registry to determine which members of the population have been diagnosed with the disease of interest. In our case, this included current and former residents of the Fort Hall Reservation, including tribal and non-tribal members. Likewise, individuals in a study population can be linked to an existing mortality registry to determine which members of the population have died and, for deceased individuals, what caused their death. Linkages between individuals and registries are performed based on several personal identifiers, such as birth date, Social Security number, first and last name, maiden name (if applicable), gender, residential address, and date of diagnosis or death. Once a linkage has been performed, an investigator can calculate the rate of newly diagnosed disease (called the incidence rate) or the mortality rate in the study population, by dividing the number of linked cases or deaths, respectively, by the amount of time spent at risk by the entire study population. More specifically, such analyses can

generate incidence and mortality rates of one study area (e.g., all Fort Hall residents) against a reference population (e.g., comparison with other tribal populations, neighboring counties, etc.). This type of analysis is commonly conducted in community health assessments, and occupational and environmental studies. It is a scientifically rigorous design and is well supported by the Statement of Work and project plan.

The observed number of deaths in the study and comparison areas was obtained from Idaho vital statistics data, the National Death Index (NDI), and other databases. Cancer incidence data from Fort Hall and statewide comparison areas were obtained from the Idaho Cancer Registry. The overall population and the age-sex or age-sex-race composition of the study and comparison areas were extracted from US Census and intra-census estimates, and population estimates from the state of Idaho through the Cancer registry and the NDI.

As discussed above the scientific literature indicates that Native American populations commonly have a distinct set of lifestyle, cultural, dietary, and clinical characteristics. Thus, it is crucial that analyses are conducted to attempt to account for the within-culture characteristics. Statistical analyses were generated to evaluate all Fort Hall tribal and non-tribal residents (as a group), and importantly, analyses were conducted among Shoshone Bannock tribal members. The reason for this is that combining different populations in an analysis is likely to produce heterogeneity in the evaluation of different demographic groups. The most informative, and scientifically and clinically relevant, analyses were based on the population-specific sub-groups. As mentioned, comparisons were made with neighboring counties and the entire state of Idaho (i.e., the health status of *all* Fort Hall residents was compared with the health status of adjacent counties, as well as the rate data from Idaho). Additionally, in an effort to account for population heterogeneity, the health status of only Shoshone Bannock tribal members was compared to rates of other Native populations. It is recognized that heterogeneity exists within Native American populations, including Shoshone Bannock tribal members; however, this demographic-specific analysis was necessary to increase the study validity and to interpret the forthcoming analyses.

Ideally, to study asthma, we would have the same type of validated high-quality data as with the cancer registry and NDI. Unfortunately, a registry for asthma does not exist, and evaluating this type of outcome is difficult because of the aforementioned methodological and analytical challenges. The study of asthma would involve individual-level medical records and personal information. Thus, we were unable to complete a scientifically valid analysis of asthma, due to the fact that we do not have registry information and because community members did not indicate a willingness to share personal medical information. In addition, given the extreme variability of medical record distribution among all residents, the infeasibility of systematically collecting relevant information from clinics outside of Fort Hall, and the differing clinical and diagnostic practices over time, we have exhausted our research efforts on a potential study of asthma.

Phase 2 Analyses: Cancer, Mortality, and Sentinel Events

Consistent with well-accepted and established research methods, we have made several contacts with representatives of the Cancer Data Registry of Idaho (CDRI). Specifically, we spoke with the head researcher of the CDRI, Chris Johnson, to discuss the logistics and methodological aspects of analyzing cancer incidence data by health district (i.e., Fort Hall). The CDRI allows for data collection at the aggregate, record, and individual level, including specified parameters of interest. The CDRI served as the cancer database to identify cases of cancer among Fort Hall residents after linkage of population parameters. In addition, we spoke with Mr. Johnson about linking residential information with the National Death Index, and he confirmed that this was standard practice and that he could perform such a linkage. We discussed comparison populations and the options for utilizing cancer and mortality rates from various databases to fully appreciate any potential relationships. We determined that results from both the cancer analyses and the mortality analyses would be examined critically to identify any potential sentinel outcomes.

Cancer Incidence Study

This study was designed to compare the rates of cancer occurrence among the Fort Hall Reservation population that had potential exposure from FMC releases from 1949 through 2001 to the rates of cancer occurrence among other residents in Idaho and among other Native American populations who were not exposed to such releases. We worked with local health providers and agencies to identify and obtain access to cancer incidence data.

In accordance with the project plan, we have followed this proposed plan of action, and the analyses and results are presented below. In our attempt to evaluate cancer incidence specifically among individuals living in Fort Hall, we investigated the Cancer Data Registry of Idaho (CDRI) and its data collection methods. After speaking with the head researcher of the CDRI, Chris Johnson, we were informed that we could collect cancer incidence data by health district, including Fort Hall. In addition, the CDRI allows for data collection at the aggregate, record, and individual level, including specified parameters of interest. The CDRI serves as a useful tool to assess residents of Fort Hall, because their data are linked with health care records from Indian Health Services located in Fort Hall. Thus, this data linkage allows for a more accurate and valid assessment of cancer incidence among residents of Fort Hall.

The basis for assessing cancer risks involves the concepts of mortality and incidence rates, which are the numbers of cancer deaths and cancer occurrences, respectively, that are observed in a given population of a specified size, usually calculated in terms of 100,000 individuals. Cancer incidence is a measure of disease burden, and it describes the occurrence of newly diagnosed cancer cases. Cancer mortality is also studied, and it provides information on both cancer incidence and the survival of individuals with a given cancer. Cancers that are not commonly fatal, such as thyroid cancer, are clearly best evaluated using incidence data. For highly fatal cancers such as pancreatic cancer and lung cancer, mortality data may reflect population-based disease burden better than cancer incidence data. However, state cancer

registries provide an unbiased and comprehensive collection and reporting of both cancer incidence and mortality -- incidence data is recorded with a very high degree of diagnostic validation and mortality data are limited by cause of death data. In evaluating cancer incidence data, it is important to understand the quality of cancer detection and the accuracy and completeness of cancer reporting to tumor registries. Also, incidence data may change as diagnostic criteria change over time, the intensity of cancer screening changes, and potential new screening methods are introduced. For cancer mortality data, there is the question of the quality of the information on the death certificates. The primary site of a cancer recorded by a registry is likely to be more accurate than on a death certificate. Nonetheless, both incidence and mortality data provide potentially useful information, and the mortality-to-incidence ratio relates to the survival rate.

The Centers for Disease Control (CDC), of the Public Health Service, provides support to most of the state cancer registries. Besides helping to maintain the registries, the CDC sees that the data are of high quality, through the National Program of Cancer Registries (NPCR), which was established in 1992. Idaho's Registry began in 1979 and joined the NPCR program in 1994. The North American Association of Central Cancer Registries (NAACCR) is an oversight group that began in 1987. Data down to the county level began to be recorded in 1995, and the NAACCR provides certification for the quality of a State's data. The registries have three levels of certification, with gold being the highest. The Idaho Registry has received a gold rating every year since this rating system began.

Through the CDC cancer registry, data are made publically available at the state level for the years 1999–2011. For the census racial category of “American Indian” or “Alaska Native” (AI/AN), Table 1 gives the number of cases for the period 1999–2011, and the cancer incidence rates, including the deaths for the states adjacent to Idaho. These data are depicted graphically in Figure 1.

Table 1. Cancer Incident Cases and Cancer Deaths among American Indians and Alaska Natives during 1999–2011

State	Incident Cases	Incidence Rate*	Cancer Deaths	Mortality Rate*
Idaho	658	366.8	228	148.9
Montana	3004	635.5	1012	247.1
Wyoming	428	404.7	161	185.7
Utah	536	223.7	214	116.0
Nevada	706	246.2	319	116.3
Oregon	2442	483.5	739	171.2
Washington	5173	523.3	1475	178.3

*Age-adjusted rates of the number of cases per 100,000 per year based on the 2000 U.S. standard population.

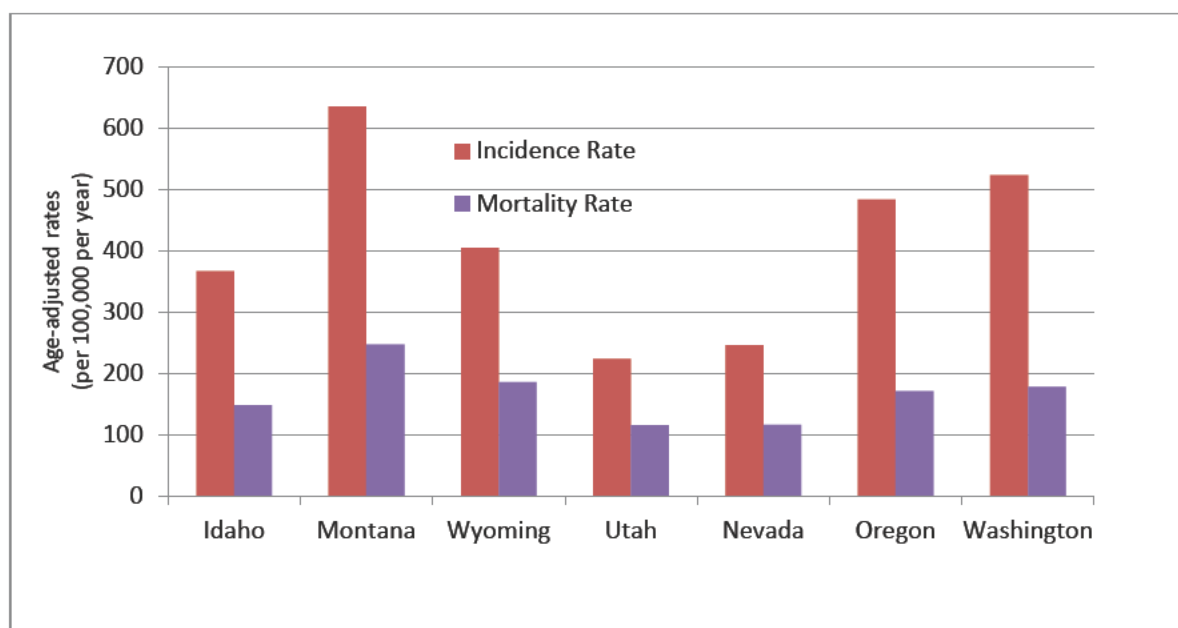


Figure 1. Cancer incidence and cancer mortality among American Indians and Alaska Natives during 1999–2011

Based on these data, both cancer incidence and mortality rates in the state of Idaho rank in the bottom half (i.e., lower cancer rates compared with the majority of other states). Indeed, Idaho has lower rates, except for the more southern states of Nevada and Utah.

Because of confidentiality considerations, the data for individual cancer sites are not given if there were fewer than a total of 16 cases during the 13-year period of 1999–2011. For the AI/AN of Idaho during 1999–2011, Table 2 gives the most common cancer sites. These findings are consistent with the most common types of cancer diagnosed in the U.S., with lung and bronchus, colorectal, prostate, and breast accounting for greatest burden of cancer in this country.

Table 2. Most Common Cancer Sites among American Indians in Idaho (1999–2011)

Cancer Site	Cancer Incident Cases	Cancer Deaths
Breast	94	16
Prostate	87	<16
Lung and Bronchus	79	46
Colon and Rectum	73	25
Non-Hodgkin's Lymphoma	26	<16
Kidney and Renal Pelvis	24	<16
Liver	22	16
Leukemia	20	<16
Corpus Uteri	20	<16

Idaho cancer incidence data for the American Indians at the census-tract level have been made available from the Idaho Cancer Registry for the 5 years 2007–2011. Chris Johnson, Idaho Cancer Registry Epidemiologist, has performed a comprehensive and detailed effort to geo-code cancer cases using U.S. census data at the census-tract level.⁴ The ability to utilize geo-coded information is a major strength of this analysis.

The incidence values are only for those Idaho counties that are Contract Health Service Delivery Areas (CHSDA).⁵ A little more than 50% of the American Indians in Idaho reside in CHSDA counties, which include the three counties of the Fort Hall reservation (Figures 2 and 3).

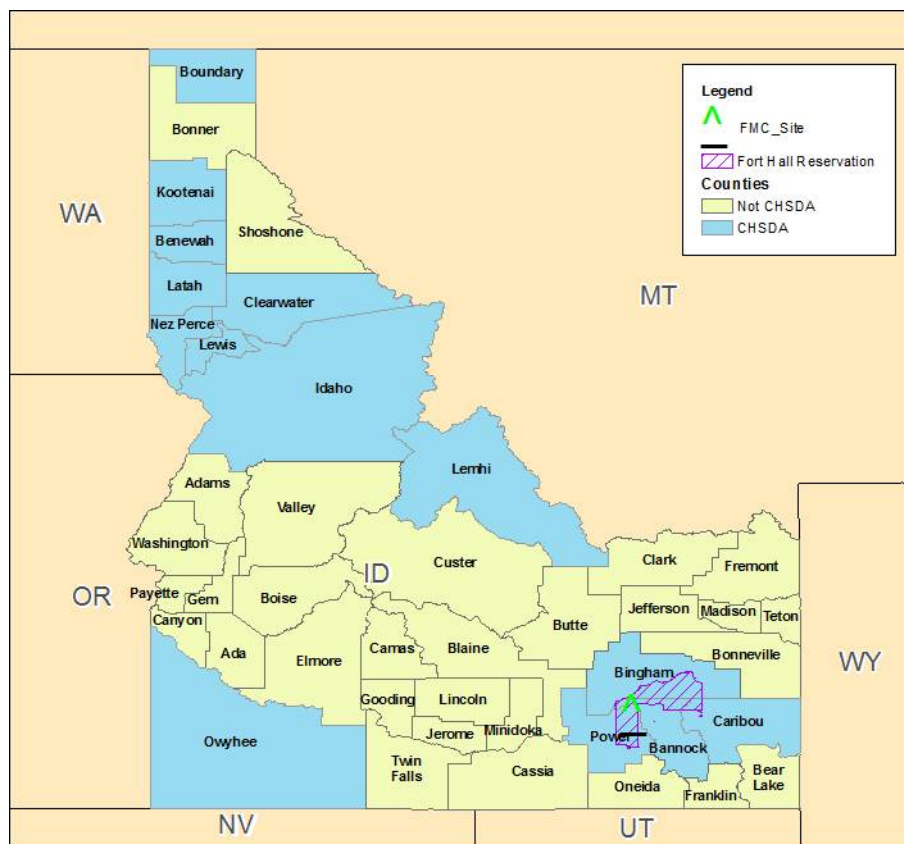


Figure 2 Idaho Counties

⁴ According to the U.S. Census Bureau: "Census Tracts are small, relatively permanent statistical subdivisions of a county or equivalent entity that are updated by local participants prior to each decennial census as part of the Census Bureau's Participant Statistical Areas Program. ... The primary purpose of census tracts is to provide a stable set of geographic units for the presentation of statistical data. Census tracts generally have a population size between 1,200 and 8,000 people, with an optimum size of 4,000 people."

⁵ Geographic area within which contract health services will be made available by the Indian Health Services to members of an identified Indian community who reside in the area. (Federal Register, Vol. 72, No. 119, June 21, 2007.) A list of CHSDA counties can be found at <http://seer.cancer.gov/seerstat/variables/countyattribs/CHSDA.pdf>

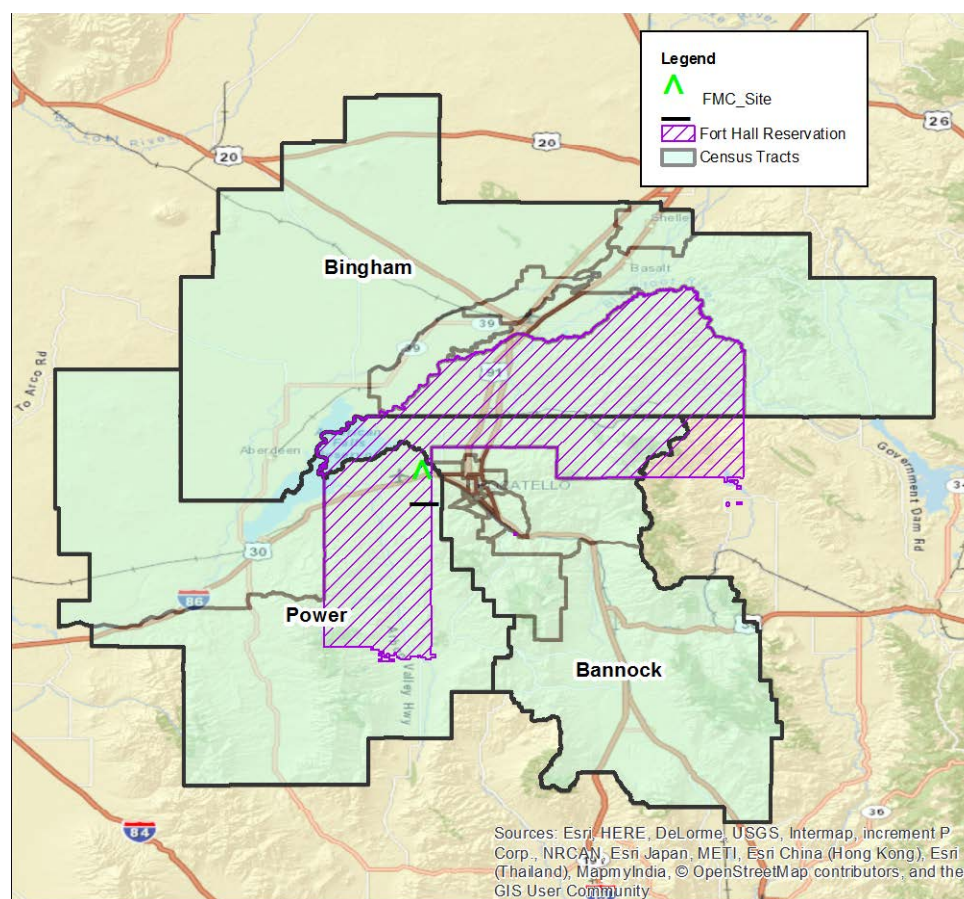


Figure 3 Map of Fort Hall Reservation and Surrounding Counties

Suppressing data with five or fewer cases, the results for cancer incidence among residents in the Fort Hall census tract and the state of Idaho during 2007–2011 are shown in Table 3 and Figure 4. The cancer sites not listed had fewer than 10 cases in the remainder of Idaho, and their small incidence rates were all less in the Fort Hall census area than in the remainder of Idaho. It is important to note that, for total cancers, the rate in the Fort Hall area was less than one-half the rate in the remainder of Idaho (259 vs. 515), and this difference was highly statistically significant ($p < 0.001$). Also, significantly fewer cases of lung cancer were observed in the Fort Hall area than in the remainder of Idaho. Although the rate for colorectal cancer (which may be due to dietary and lifestyle factors) is modestly greater in Fort Hall, the difference with the remainder of Idaho is not statistically significant.

Table 3. Cancer incidence (2007–2011) among American Indians in Fort Hall and Remainder of Idaho CHSDA Counties

Cancer Site	Fort Hall Census Tract		Remainder of Census Tracts in CHSDA Counties in Idaho	
	Cancer Cases	Incidence Rate [#]	Cancer Cases	Incidence Rate
All Sites *	35	259 (47)	174	515 (44)
All Sites Males	17	310 (87)	74	482 (63)
All Sites Female *	18	234 (59)	100	548 (62)
Lung & Bronchus **	<6	6 (6)	23	89 (21)
Colorectal	9	82 (30)	22	66 (16)
Female Breast	<6	53 (27)	27	140 (30)
Male Prostate	6	102 (48)	21	125 (31)

* Fort Hall cancer incidence rate is statistically less than the rate for the remainder of Idaho with $p=0.001$ and ** $p=0.05$

Age adjusted to the 2000 standard U.S. population. Rate per 100,000 (standard error).

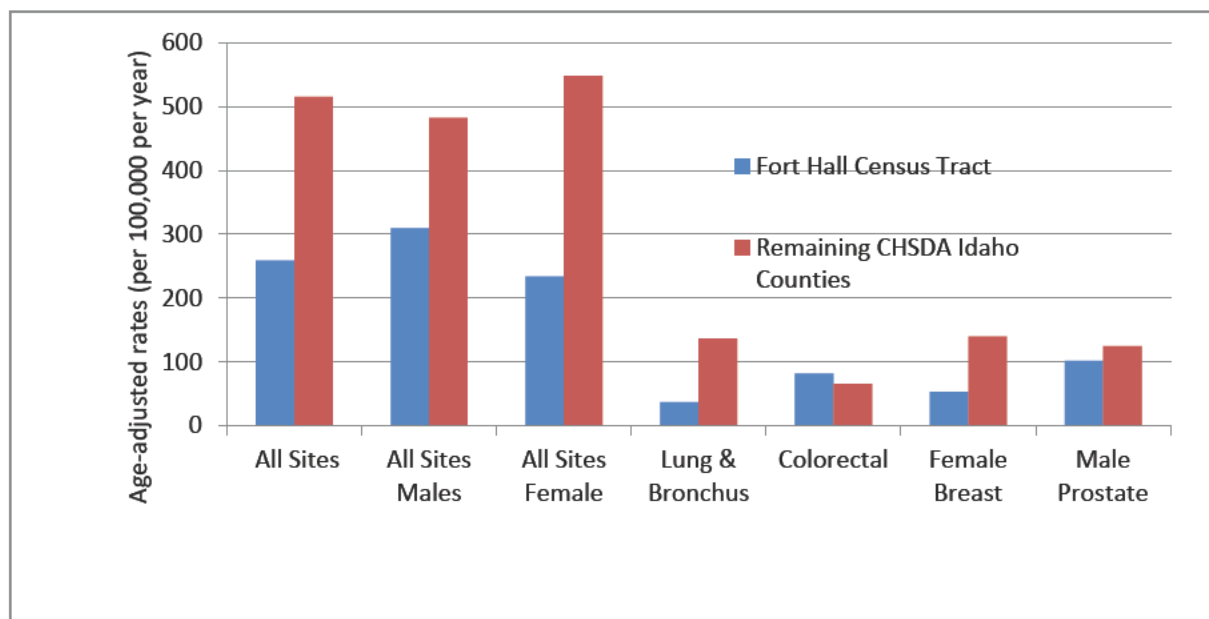


Figure 4 Cancer Incidence (2007–2011) among American Indians in Fort Hall and Remainder of Idaho CHSDA Counties

The American Indian population in the Fort Hall census tracts is 3,624, while the American Indian population is 6,719 in the three Fort Hall counties. It is therefore of interest to compare the cancer rates for the census tracts and the larger three county areas, which includes the Fort Hall census tracts. Table 4 provides these comparison values. The Table shows that the cancer rates in the Fort Hall census area are either less than or the same as the greater three county areas. For completeness, Table 5 and Figure 5 compare the three-county Fort Hall area with the remainder of Idaho CHSDA counties.

Table 4. Cancer Incidence (2007–2011) among American Indians in the Fort Hall census tracts, and Incidence in the Fort Hall counties of Bannock, Bingham, and Power

Cancer Site	Fort Hall Census Tract		Three Counties of Fort Hall	
	Cancer Cases	Incidence Rate	Cancer Cases	Incidence Rate
All Sites	35	259 (47)	81	364 (44)
All Sites Males	17	310 (87)	39	424 (80)
All Sites Female	18	234 (58)	42	334 (55)
Lung & Bronchus	<6	6 (6)	7	36 (15)
Colorectal	9	82 (30)	20	102 (25)
Female Breast	<6	53 (27)	7	58 (23)
Male Prostate	6	102 (48)	13	127 (40)

Table 5. Cancer incidence (2007–2011) among American Indians in the three Fort Hall counties, and cancer incidence in the remaining CHSDA Idaho counties

Cancer Site	Three Counties of Fort Hall		Remainder of CHSDA Idaho Counties	
	Cancer Cases	Incidence Rate	Cancer Cases	Incidence Rate
All Sites*	81	364 (44)	128	503 (50)
All Sites Males	39	424 (80)	52	435 (67)
All Sites Female*	42	334 (55)	76	565 (74)
Lung & Bronchus	7	36 (15)	17	85 (23)
Colorectal	20	102 (25)	11	44 (16)
Female Breast*	7	58 (23)	24	165 (37)
Male Prostate	13	127 (40)	14	115 (34)

* Fort Hall cancer incidence rate is statistically less ($p < 0.05$) than the rate for the remainder of CHSDA Idaho counties.

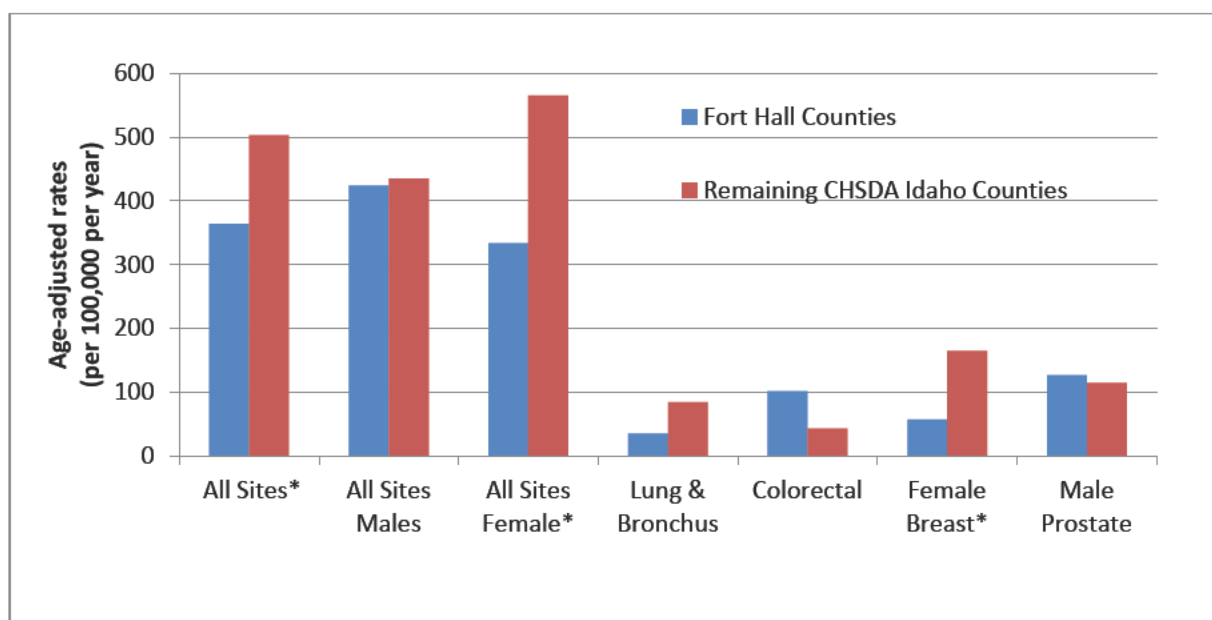


Figure 5 Cancer Incidence (2007–2011) among American Indians in the three Fort Hall Counties, and Cancer Incidence in the Remaining Idaho Counties

The data for the years 2007–2011 clearly show that cancer incidence is lower in the Fort Hall census-tract areas than in both the surrounding three counties and also the remaining areas of the state of Idaho. For all cancers combined, the rate for Fort Hall is about one-half that of the remainder of Idaho, and with lung cancer, the rate is less than one-third.

All-Cause Mortality Study

This study was designed to assess the mortality rates among the Fort Hall Reservation population who may have incurred exposure from FMC releases during 1949–2001 to the mortality rates among other residents in Idaho, and among other Native American populations who were not exposed to such releases. As with the cancer incidence study, we have followed this proposed plan of action, and the analyses and results are presented below.

The National Center for Health Statistics (NCHS) of the CDC collects and codes all death certificates in the United States. These data, coupled with data from the Census Bureau, then provide mortality rates for various causes. The data are available by location, age, race, gender, etc. Using these data, one can estimate and compare mortality rates for a given cause of death by age, gender, race, etc. The data is publically available through the CDC website.

For the 14-year period 1999–2012, the age-adjusted mortality rates for American Indians and Alaska Natives are given in Table 6 and Figure 6 for Idaho and its adjacent states. As with the cancer data, Idaho's mortality rates are less than its eastern neighbors, Montana and Wyoming, but greater than its southern neighbors, Nevada and Utah. Overall, Idaho ranks exactly in the middle of all states in Table 6.

Table 6. Total Mortality and Age-Adjusted Rates for American Indians and Alaska Natives during 1999–2013

State	Deaths	Mortality Rate*
Idaho	1816	861
Montana	6942	1260
Wyoming	1470	1184
Utah	2193	808
Nevada	2497	652
Oregon	4463	776
Washington	10127	942

* Age-adjusted rates of the number of cases per 100,000 per year, based on the 2000 U.S. standard population.

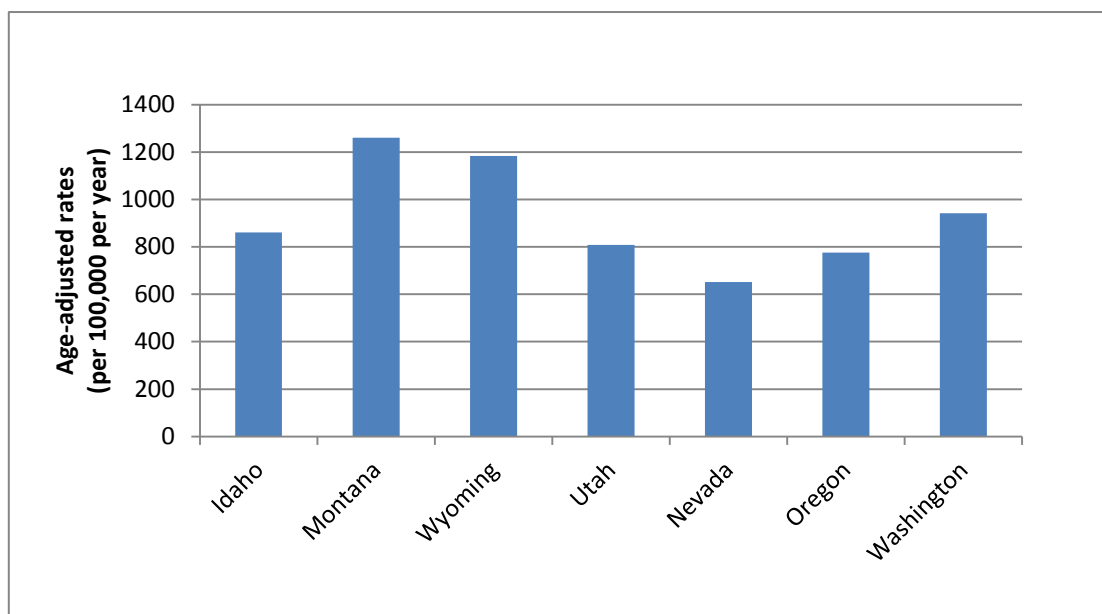


Figure 6 Age-Adjusted Total Mortality Rates for American Indians and Alaska Natives during 1999–2012

Table 7 shows the rates for the most common mortality causes for American Indians in the counties of Fort Hall—namely Bingham, Bannock, Power (Figure 3)—and those of the remaining Idaho counties. The table shows that the rates for the Fort Hall counties are greater than those of the other counties. This is in direct contrast with the cancer incidence findings. It should be recognized, however, that the Fort Hall counties include individuals who do not reside in Fort Hall, while the cancer incidence data used the more accurate census-tract data (see the map for details). Furthermore, in terms of cancer, cancer incidence data provide a more accurate

reflection of disease burden in a population, because mortality statistics are heavily influenced by access to care and treatment options.

Table 7. Major Causes of Death in American Indians and Alaska Natives (1999–2013)

Cause of Death	Fort Hall Counties		Remainder Counties in Idaho	
	Deaths	Rate	Deaths	Rate
Cancer	88	170.2 (19.5)	195	138.1 (11.3)
Diseases of the Circulatory System [#]	141	318.7 (29.1)	268	215.2 (14.9)
Diseases of the Digestive System ^{##}	108	167.3 (17.4)	102	55.7 (6.3)
Diseases of the Respiratory System	46	105.4 (16.8)	94	76.8 (8.9)
Endocrine and Metabolic Disease ^{##}	76	160.0 (19.8)	80	57.6 (7.3)
Infectious Diseases	18	Unreliable*	35	17.9 (3.3)
Mental or Behavioral Disorders	20	47.0 (11.4)	22	19.6 (4.6)
Nervous System Disease	<10	Unreliable*	24	18.0 (4.2)
Genitourinary System Disease	22	46.7 (10.9)	22	18.1 (4.4)
External Causes ^{##}	151	167.9 (14.5)	208	77.6 (6.0)
Total Mortality ^{##}	723	1302.2 (54.2)	1093	717.4 (25.4)

A statistical difference between Fort Hall and the remainder counties at $p < 0.05$, ## $p < 0.001$

* With less than 20 deaths, the estimated mortality rate is considered to be unreliable.

The CDC data for 1999–2013 can also be reported yearly. Table 8 shows the mortality rates for the two periods 1999–2005 and 2006–2013. More divisions is a problem since data less than 10 cases are suppressed and rates based on fewer than 20 cases are considered to be unreliable. Table 8 indicates that mortality rates for most causes have decreased, both in Fort Hall and in Idaho in general. The digestive disease mortality in the Fort Hall Counties is primarily to cirrhosis of the liver resulting from alcohol consumption (63 of the 108 deaths) and the endocrine mortality consists mostly of mortality due to diabetes (64 of the 76 deaths), which is likely due to genetic traits and/or diet and lifestyle factors.

Table 8. Changes in Age-Adjusted Mortality Rates for Major Causes of Death in American Indians and Alaska Natives (1999–2005 compared to 2006–2013)

Cause of Death	Fort Hall Counties		Remainder Counties in Idaho	
	1999–2005	2006–2013	1999–2005	2006–2013
Cancer	199.6 (34.6)	147.9 (22.5)	150.1 (19.6)	133.6 (14.0)
Diseases of the Circulatory System	322.3 (47.0)	318.8 (37.5)	287.4 (29.8)	180.6 (16.8) [#]
Diseases of the Digestive System	186.3 (29.8)	155.2 (21.0)	62.9 (11.1)	52.6 (7.8)
Endocrine and Metabolic Disease	230.5 (38.3)	115.4 (21.2)	83.2 (15.6)	45.3 (7.8)
External Causes	207.4 (24.1)	139.3 (17.9)	79.3 (8.9)	75.6 (7.9)
Total Mortality	1477 (92)	1188 (67)	842 (47)	652 (30) [#]

A statistically significant decrease at $p < 0.05$.

Table 9 compares the mortality of the Fort Hall counties with the remaining CHSDA counties in Idaho. The mortality rates compare more closely with each other than in Table 7, which includes all Idaho counties and not just the CHSDA counties. The mortality rates between Fort Hall and CHSDA counties are similar likely because the comparison group is comparable in terms of genetics, diet, lifestyle, access to care, and treatment options.

Table 9 Major Causes of Death in American Indians and Alaska Natives (1999–2013)

Cause of Death	Fort Hall Counties		Remainder CHSDA Counties in Idaho	
	Deaths	Rate	Deaths	Rate
Cancer	88	170.2 (19.5)	102	181.7 (20.2)
Diseases of the Circulatory System	141	318.7 (29.1)	164	327.6 (28.6)
Diseases of the Digestive System**	108	167.3 (17.4)	65	90.2 (12.7)
Diseases of the Respiratory System	46	105.4 (16.8)	59	111.6 (16.6)
Endocrine and Metabolic Disease*	76	160.0 (19.8)	61	109.9 (15.8)
Infectious Diseases	18	Unreliable#	20	22.9 (5.4)
Mental or Behavioral Disorders	20	47.0 (11.4)	10	Unreliable#
Genitourinary System Disease	22	46.7 (10.9)	13	Unreliable#
External Causes	151	167.9 (14.5)	131	124.7 (11.8)
Total Mortality**	723	1302.2 (54.2)	668	1070.3 (48.0)

* A statistical difference between Fort Hall and the remainder CHSDA counties $p < 0.05$. ** $p < 0.01$

With less than 20 deaths the estimated mortality rate is considered to be unreliable.

The Fort Hall area is in the southeastern area of Idaho, while most of the Idaho American Indians who are not in the Fort Hall area reside primarily in the western part of Idaho, near Oregon and Washington. Therefore, it seems appropriate to also evaluate mortality rates near Fort Hall but to the east; namely, in Fremont County, Wyoming. The Wind River Indian Reservation is in Fremont County and is the home of the Eastern Shoshone and Northern Arapaho tribes of North America, while the Fort Hall area is home to both the Shoshone and Bannock tribes. The population of American Indians in Fremont County as of the 2010 census is 8,498, while the population in Bannock, Bingham, and Power counties is 2,619, 2,970, and 179, respectively for a total of 5,768. Table 10 presents the mortality rates for the Fort Hall counties and Fremont County. Overall, and for each cause of mortality, the rates were higher in the Wyoming county comparison population. The one exception was endocrine and metabolic disease mortality, which is primarily due to diabetes. The number of deaths and the mortality rate for diabetes were 64 and 134.0 for the Fort Hall counties, respectively. For Fremont County, the corresponding values were 70 and 113.8, respectively.

Table 10. Major Causes of Death in American Indians and Alaska Natives (1999–2013)

Cause of Death	Fort Hall Counties		Fremont County ^a , Wyoming	
	Deaths	Rate	Deaths	Rate
Cancer	88	170.2 (19.5)	141	223.4 (20.6)
Diseases of the Circulatory System	141	318.7 (29.1)	199	332.1 (26.0)
Diseases of the Digestive System	108	167.3 (17.4)	173	201.1 (16.3)
Diseases of the Respiratory System	46	105.4 (16.8)	89	139.3 (16.8)
Endocrine and Metabolic Disease	76	160.0 (19.8)	83	134.8 (16.5)
Infectious Diseases	18	Unreliable [#]	28	43.3 (9.2)
Mental or Behavioral Disorders	20	47.0 (11.4)	26	33.7 (7.6)
Nervous System Disease	<10	Unreliable [#]	26	61.6 (13.3)
Genitourinary System Disease	22	46.7 (10.9)	30	48.7 (10.0)
Abnormal Clinical Findings	19	Unreliable [#]	21	30.5 (8.3)
External Causes*	151	167.9 (14.5)	275	238.6 (15.5)
Total Mortality*	723	1302.2 (54.2)	1142	1537.4 (52.2)

^a Fremont county is a CHSDA county, as are the Fort Hall counties.

[#] With fewer than 20 deaths, the estimated mortality rate is considered to be unreliable.

* A statistical difference between the Fort Hall counties and Fremont county $p < 0.01$.

Sentinel Health Events

Health consequences of chronic environmental exposures can be manifested in a variety of ways that make it difficult to determine a precise association. We have reviewed the literature and discussed certain outcomes with community residents. We also explored the occurrence of sentinel diseases that could potentially be related to phosphorus exposure,⁶ and we investigated the rates of other diseases, such as lupus and rheumatoid arthritis. The literature suggests that Native American ethnicity can be considered a risk factor for the development of rheumatoid arthritis, because RA is almost four times more prevalent among Native Americans than Europeans. Specifically, the highest prevalence rates of RA have been recorded in the Pima,

⁶ Based on our review of the peer-reviewed literature, the only rare disease that has occurred previously is “phossy jaw” also known as phosphoric necrosis of the jaw. This was a common disease among workers in the match industry during the 19th and early 20th centuries, who were exposed to heated fumes containing phosphorous. Based on review of exposure information from the project portal, phosphorus was an exposure of concern. However, to fully evaluate whether conditions related to phosphorus exposure, namely “phossy jaw,” are associated with residing in the Fort Hall community, we would need detailed individual-level data with exposure estimations, which we have neither.

Chippewa, and Yakima tribes. In addition, many Native Americans carry a high-risk epitope, placing them at even greater risk.⁷ Similarly, we note that literature suggests that lupus is more frequent among minorities, including Native Americans, than among those of Caucasian descent.⁸ As mentioned previously, and because of a lack of individual-level data, we determined it to be feasible to evaluate sentinel events in the context of cancer and mortality only. Based on the cancer analyses reported in this document, no sentinel cancer events were observed. In fact, most cancer rates were less than those in the comparison populations. Similarly, no sentinel mortality events were observed based on the analyses reported in this document.

Childhood Asthma

The initial objectives were to determine whether the closure of the FMC plant in 2001 significantly decreased the rate of new-onset asthma and the prevalence of asthma exacerbations among children living on the Fort Hall Reservation, and whether particulate air pollution emitted from the FMC plant increased the risk of new-onset asthma or asthma exacerbations in children. However, given the complexities of evaluating childhood asthma, such as estimating environmental exposures, variable case definitions, differing diagnostic practices over time, identifying accurate medical charts and records, enumerating study populations without selection bias, and obtaining informed consent and willingness to participate, the potential analyses of asthma in the Fort Hall are could not be performed.

Three site visits were conducted by the research team between during 2011–2012, to assess the extent to which we could identify viable data sources and obtain access to relevant non-clinical records. While much of the descriptive demographic data for the current population of the Fort Hall Reservation were obtained from various resources (the Department of Public Safety, the Land Use Policy Commission, the Land Information Services, the Enrollment Department, and the Fort Hall Agency of the Bureau of Indian Affairs), we were not able to obtain historical clinical data for the period 1990–2005.

To provide a clinical assessment of asthma, we visited and had several discussions with staff from the Indian Health Center. Outpatient health care for the residents of the Fort Hall Reservation is, and was during the period of interest, provided at many facilities and by many institutions. This circumstance produces great variability and limits the ability to conduct a formal epidemiologic study. Eligible residents can seek care first at the Not-Tsoo Gah-Nee Indian Health Center, which opened in October 1990 and includes an Outpatient Clinic and Dental, Pharmacy, Lab, X-ray, Optometry, Podiatry, Audiology, and Contract Health services. Implementation of *some* administrative and medical electronic records started in 1996, but full electronic medical records have been implemented only since 2006. Many residents of the Fort Hall Reservation, including residents not eligible to use the Heath Center and some eligible

⁷ Molokhia, M. et al. 2000. Review. Risk for rheumatic disease in relation to ethnicity and admixture. *Arthritis Res.* 2(2):115–125.

⁸ Rus, V, A. Hajeer M.C. Hochberg. 2001. Chapter 7. Systemic lupus erythematosus. In: A.J. Silman and M.C. Hochberg (Eds.) *Epidemiology of the rheumatic disease*. 2nd edition. Oxford University Press, New York.

residents, do not use the Heath Center for all of medical services, including for pediatric primary care, for specialty treatment, or for medications.

Other outpatient facilities used by Fort Hall Reservation residents for childhood asthma care include the Pocatello Children's Clinic and other private pediatricians or family practices in Pocatello, Blackfoot, or Idaho Falls. To our knowledge, no inpatient care is provided on the Reservation, and residents use the hospitals in Pocatello, Blackfoot, Idaho Falls, and as far as Salt Lake City, Boise, Portland, Seattle, or Phoenix, where the IHS inpatient facility for the region is located. Although medications prescribed by Not-Tsoo Gah-Nee Indian Health Center providers are dispensed free of charge to eligible patients, other residents and some eligible patients choose to obtain medications at local pharmacies or by mail, using their health insurance or paying out of pocket. Thus, asthma medication information from the Not-Tsoo Gah-Nee Indian Health Center would likely be incomplete, and the patterns of use may have varied over time, resulting in heterogeneous study populations.

In terms of insurance data, while medical care and medications are provided free of charge to eligible patients at the Not-Tsoo Gah-Nee Indian Health Center, many patients receive care outside of the Reservation, which is covered by their employers' insurance, private insurance, the tribal insurance, Medicare, or Medicaid. Furthermore, some residents change from one payer to another over time, or depending on the type of services they need. Thus, comprehensive insurance claims data on Fort Hall Reservation residents are not available.

We also evaluated the feasibility of using other sources of information. For example, we identified the Youth Risk Behavior Surveillance System (YRBSS). This system allows for analysis of national, state, and local YRBSS data from 1991–2011, including data from middle schools and high schools. In addition, we looked into the related and more comprehensive Behavior Risk Factor Surveillance System (BRFSS), which began in the U.S. in 1984. This surveillance system is the world's largest ongoing telephone health survey system that aims to track health conditions and risk behaviors in the United States. On speaking with the BRFSS state coordinator of Idaho, Chris Murphy, we learned that, while BRFSS collects information on asthma, the data are limited and primarily restricted to *adults* for most years (not the intended study population), because the questions change annually. Further discussion regarding YRBSS and BRFSS revealed that data regarding asthma among children and young adults in Fort Hall were extremely limited, due to insufficient resources, lack of data, and variable reporting and record keeping practices.

Because of the methodological limitations discussed above and the infeasibility of conducting a formal asthma study based on exposure information and individual clinical, lifestyle, socio-economic, and geographic data, Exponent sought to work with a Fort Hall health and/or medical liaison to abstract relevant asthma diagnostic information for an evaluation of the occurrence of asthma. However, based on discussion with the Northwest Portland Area Indian Health Board, Exponent would still be required to obtain informed consent from individual patients who would be willing to release their medical records. Although the data abstraction initiative may have provided some information, albeit limited, Exponent became aware of the informed consent complexities after second progress report. Furthermore, there were greater challenges than expected with the record keeping of medical files. Thus, this effort was deemed infeasible.

Attachment A

Results of Willingness-to-Participate Survey

Table A-1. Characteristics of Survey Participants in Fort Hall, Idaho (August–October 2012), n=351

	No.	%
Participation		
Yes	319	90.8
No	32	9.1
Reason for refusal (if applicable) a		
Too busy	6	18.2
Not interested	13	39.4
Poor health	1	3.0
No personal benefit	6	18.2
Survey too confusing	1	3.0
Other	13	39.4
Age Distribution (years)		
≤20	8	2.5
21-29	31	9.8
30-39	41	12.9
40-49	50	15.7
50-59	88	27.7
60-69	64	20.1
70-79	30	9.4
≥80	6	1.9
Sex		
Male	144	46.8
Female	164	53.2
	308	
Shoshone-Bannock Tribal Member		
Yes	220	69.6
No	96	30.4
Current District		
Fort Hall/Buffalo Lodge	142	50.4
Lincoln Creek	9	3.2
Ross Fork	17	6.0

	No.	%
Gibson	77	27.3
Bannock Creek	37	13.1
	282	
Mean number of adults and children in household	3.04 ± 1.78 (range, 1-10)	
Mean number of children <18 years in household	0.96 ± 1.46 (range, 0-7)	
Preferred survey format b		
In person with an interviewer	82	25.7
By myself with a paper questionnaire	215	67.4
On the telephone with an interviewer	68	21.3
By myself with an online (computer) questionnaire	87	27.3
a Respondents could choose more than one answer		
b At least one response (n=314); at least two responses (n=100); at least three responses (n=26); at least four responses (n=12)		

Table A-2. Likelihood of Answering Questions on the Following Topics in a Future Questionnaire

How likely would you be to answer questions about:	For myself		For household members	
	No.	%	No.	%
Residential History?				
Very likely	179	59.5	130	53.7
Likely	90	29.9	63	26.0
Neither likely nor unlikely	24	8.0	23	9.5
Unlikely	4	1.3	13	5.4
Very unlikely	4	1.3	13	5.4
	301		242	
Diet?				
Very likely	165	55.2	122	51.3
Likely	94	31.4	65	27.3
Neither likely nor unlikely	30	10.0	27	11.3
Unlikely	4	1.3	11	4.6
Very unlikely	6	2.0	13	5.5
	299		238	
Sources of food?				
Very likely	164	55.6	133	55.0
Likely	99	33.6	67	27.7
Neither likely nor unlikely	24	8.1	20	8.3
Unlikely	2	0.7	7	2.9
Very unlikely	6	2.0	15	6.2
	295		242	
Sources of water?				
Very likely	181	62.6	155	62.2
Likely	82	28.4	51	20.5
Neither likely nor unlikely	18	6.2	18	7.2
Unlikely	4	1.4	9	3.6
Very unlikely	4	1.4	16	6.4
	289		249	

How likely would you be to answer questions about:	For myself		For household members	
Use of local plants in ceremony?				
Very likely	142	49.7	111	45.9
Likely	58	20.3	46	19.0
Neither likely nor unlikely	48	16.8	38	15.7
Unlikely	18	6.3	17	7.0
Very unlikely	20	7.0	30	12.4
	286		242	
Occupation?				
Very likely	161	54.6	131	55.5
Likely	93	31.5	60	25.4
Neither likely nor unlikely	24	8.1	22	9.3
Unlikely	7	2.4	5	2.1
Very unlikely	10	3.4	18	7.6
	295		236	
Tobacco smoking?				
Very likely	159	52.8	121	51.7
Likely	80	26.6	52	22.2
Neither likely nor unlikely	32	10.6	29	12.4
Unlikely	7	2.3	6	2.6
Very unlikely	23	7.6	26	11.1
	301		234	
Physical activity?				
Very likely	166	54.4	128	55.4
Likely	101	33.1	59	25.5
Neither likely nor unlikely	23	7.5	20	8.7
Unlikely	8	2.6	9	3.9
Very unlikely	7	2.3	15	6.5
	305		231	
Alcohol consumption?				
Very likely	149	49.7	116	50.2

How likely would you be to answer questions about:	For myself		For household members	
Likely	77	25.7	45	19.5
Neither likely nor unlikely	35	11.7	32	13.9
Unlikely	11	3.7	11	4.8
Very unlikely	28	9.3	27	11.7
	300		231	
Access to healthcare?				
Very likely	173	57.1	135	56.3
Likely	94	31.0	61	25.4
Neither likely nor unlikely	22	7.3	19	7.9
Unlikely	7	2.3	7	2.9
Very unlikely	7	2.3	18	7.5
	303		240	
Current health (illnesses, diseases)				
Very likely	167	55.3	128	54.0
Likely	97	32.1	62	26.2
Neither likely nor unlikely	21	7.0	20	8.4
Unlikely	6	2.0	7	3.0
Very unlikely	11	3.6	20	8.4
	302		237	
Release of medical records				
Very likely	109	34.9	73	31.9
Likely	98	31.4	51	22.3
Neither likely nor unlikely	45	14.4	47	20.5
Unlikely	27	8.7	23	10.0
Very unlikely	33	10.6	35	15.3
	312		229	

DRAFT FOR DISCUSSION PURPOSES ONLY

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 10**

IN THE MATTER OF:

U.S. EPA Region 10
Docket No. CERCLA-10-2103-0116

FMC Operable Unit of the Eastern
Michaud Flats Superfund Site

FMC Corporation,

Respondent.

Proceedings under Section 106(a)
and 122(b)(3) of the Comprehensive
Environmental Response, Compensation,
and Liability Act, 42 U.S.C. §§ 9606(a) and
9622(b)(3).

**AGREEMENT AND FIRST MODIFICATION TO ADMINISTRATIVE ORDER
REGARDING RESPONSE COST PAYMENTS TO BE PLACED IN SPECIAL
ACCOUNT**

1. The U.S. Environmental Protection Agency (EPA) issued Unilateral Administrative Order for Remedial Design and Remedial Action, EPA Docket No. CERCLA-10-2103-0116 (Order), to FMC Corporation as the Respondent on June 10, 2013 for FMC Operable Unit of the Eastern Michaud Flats Superfund Site (Site).
2. By letter of June 20, 2013, Respondent provided its notice of intent to comply with the Order. Respondent has been performing the Remedial Design and Remedial Action work for the FMC Operable Unit.
3. The Order provided in Section XXII on "Payment of Response Costs" that Respondent "shall pay EPA all Response Costs incurred or to be incurred in connection with this Order, including the costs that EPA incurs overseeing Respondent's implementation of the Order.
4. The Respondent agrees to pay EPA all Response Costs, as defined in Section XXII of the Order, to be incurred in connection with the Order. The EPA and the

Respondent agree that all EPA response costs paid by Respondent from the date of this Agreement forward, may be deposited by the EPA in the Eastern Michaud Flats Superfund Site/FMC Operable Unit Special Account 105X to be retained and used to conduct or finance response action at or in connection with the Site, or to be transferred by EPA to the EPA Hazardous Substance Superfund.

5. The Respondent is advised that violation of Paragraph 4 may subject it to civil penalties as provided in sections 109 and 122 of CERCLA, 42 U.S.C. §§ 9606 and 9622.

Commented [A1]: May strike to get agreement if respondent objects

6. The scope of this Agreement is limited to the matters addressed above. All provisions of the Order remain in full force and effect to the extent not superseded by the limited terms of this Agreement. Beyond the terms of this Agreement, nothing herein changes Respondent's statements in its June 20, 2013 letter of intent, and Respondent reserves all of its rights and defenses with regard to the Order.

So Agreed and Ordered, this _____ day of _____, 2015.

By: _____
EPA/ ECL Office Director

And Agreed to by:

FMC Corporation Authorized Official

SEP 14 LETTER OF AUTHORIZATION

LOA 010 T

STUDY MANAGEMENT TEAM (SMT) AND APPROVED VENDORS

January 1, 2016 through June 30, 2016

SEP 14 Study Management Team Members are responsible for a number of activities associated with the project including, but not limited to:

1. Project administration and oversight, including schedule and budget
2. Project conformance to the Consent Decree requirements and other EPA SEP guidance
3. Study Design Panel selection
4. Approval of Study Design Panel recommendations
5. Approval and management of contractors
6. Development and management of communication and education plan
7. Development and management of statements of work for authorized vendors.

This Letter of Authorization (LOA) authorizes Members of the SEP 14 Study Management Team (SMT) and Approved Vendors to carry out work authorized by the SMT and charge amounts to the SEP 14 project funds administered by *de maximis, inc.* as described below.

SMT Members receiving hourly compensation for activities authorized by the SMT are provided a maximum of thirty (30) billable hours for the 1st two quarters of 2016 unless an agreement exists independent of this LOA expressly providing otherwise.

SMT Members who are employees of either the Tribes or FMC will not receive compensation from SEP 14 funding for their participation (excluding travel related expenses) for SEP 14 work.

SMT Members and Approved Vendors receiving hourly compensation from SEP 14 funds will maintain detailed time records by date describing activities under this LOA and will provide work descriptions in the invoices they submit for their work. The invoices will provide the information required under the *de maximis* invoice template and attach originals (or photocopies if authorized by the SMT) of the receipts for costs submitted for reimbursement.

Each invoice submitted under this LOA shall cover a one-month calendar period and must be submitted not later than the 20th day of the following month to be eligible for payment. In exceptional circumstances the SMT may approve submittal of individual invoices after the 20th day deadline. No charges outside the monthly calendar period of an invoice will be paid. No payment shall be made for hours billed in excess of those authorized under this LOA unless those hours are approved by the SMT in advance of the

additional work proposed to be performed. SMT-approved exceedances must be noted on the monthly invoice. Each vendor shall prepare a separate monthly invoice, which may be submitted for review and payment in conjunction with other invoices at the vendor's option.

All invoices for LOA 010 T costs must be submitted (electronically or postmarked) to de maximis for receipt no later than July 20, 2016 to remain eligible for reimbursement from the SEP14 account. LOA 010 T will be closed out no later than July 20, 2016.

Reasonable SMT and Approved Vendor expenses associated with the work authorized under this LOA shall be reimbursed and mileage costs for personal vehicle use for non-routine SEP 14 business shall be reimbursed at the prevailing IRS rate.

Approved By SMT:

By email: Robert Forbes
Liz Davis
Dave Heineck
Roz Schoof
Susan Hanson
Danny Stone

March 8, 2016

**SMT Members and
Approved Vendors**

LOA 010T

FMC:

SMT:

Liz Davis	Not approved as to compensation for time
Bob Forbes	Not approved as to compensation for time
Dave Heineck	Not approved as to compensation for time
Roz Schoof	

Approved Vendors: DEFERRED 1ST QUARTER, 2010 ON TRIBAL MOTION

Nick Gudka	See LOA 010 D
Paul Yochum	See LOA 010 D
Dina Johnson	See LOA 010 D
Rob Hartman	See LOA 010 D

Approved Vendor: DEFERRED June 15, 2011

Dina Johnson	See LOA 010D
--------------	--------------

Approved Vendor:

Paul Yochum: 8 hours for Exponent/SMT/FHBC meetings January, 2012

Tribes:

SMT:

Susan Hanson	
Hobby Hevewah	
Danny Stone	Not approved as to compensation for time